

## REMARKS

### 1. Objection to Claim 60

Claim 60 was objected to due to the recitation "mount", which should have been "amount". The claim has been amended accordingly.

### 2. Rejection of Claims 49-58 under 35 U.S.C. 112, first paragraph

Claims 49-58 were rejected under 35 U.S.C. 112, first paragraph as not enabled for the reasons of record. Specifically, the Examiner argued that the invention as recited cannot work because if the substrate lipid and the enzyme are not included in the assay, the activity cannot be quantitated.

Applicants respectfully note that phosphoinositide kinase, as the enzyme whose activity to be measured, is endogenous or added to the test sample. The substrate phosphoinositide lipid, which is phosphorylated by phosphoinositide kinase to produce the target lipid which is in turn quantitated by the described competition assay, may be either endogenous to or added to the sample

Applicants have amended claim 49 to clarify this point and respectfully argue that a contacting step is included in the claim as amended by the recitation describing substrate lipid as being either endogenous or added to an unknown endogenous amount of phosphoinositide kinase.

In view of the foregoing, Applicants respectfully request that the Examiner's rejection of claims 49-58 under 35 U.S.C. 112, first paragraph be withdrawn.

### 3. Rejection of Claims 60-66 under 35 U.S.C. 112, first paragraph

Claims 60-66 were rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement for the reasons of record. Specifically, the Examiner argued that the specification does not disclose instructions for using an assay kit of the present invention.

Applicants respectfully traverse the rejection. Although the specification does not literally disclose that instructions are a necessary or desired component of a kit, one of skill in the art would readily understand that a complex assay such as that described in the

present application would inherently contain minimal written or pictographic instructions to aid the end user in conducting the assay and/or interpreting the results.

In view of the foregoing, Applicants respectfully request that the Examiner's rejection of claims 60-66 under 35 U.S.C. 112, first paragraph be withdrawn.

4. Rejection of Claims 49-58 and 60-66 under 35 U.S.C. 112, second paragraph

Claims 49-58 and 60-66 were rejected under 35 U.S.C. 112, second paragraph for the reasons of record.

a. With respect to claim 49, regarding the Examiner's argument that the preamble does not correlate with the body of the claim, Applicants have amended the claim to recite a method where decreases in signal from the competing lipid correlate negatively with the presence of the target lipid, which correlates positively with the amount of phosphoinositide kinase activity.

b. With respect to claim 49, regarding the Examiner's argument that "which is" is vague and indefinite, Applicants have amended the claim to clarify that the target lipid is a phosphorylation product of a reaction between a phosphoinositide kinase and a substrate phosphoinositide lipid.

c. With respect to claim 49, regarding the Examiner's argument that the recitation "measuring decreases of said ... correlates positively with said phosphoinositide kinase activity" is vague and indefinite, Applicants have amended the claim as suggested by the Examiner.

d. With respect to claim 60, regarding improper dependency to a canceled claim, Applicants have amended the claim to depend from claim 49.

e. With respect to claim 60, regarding the Examiner's arguments that the recitation of "which is a phosphorylation product..." renders the claim vague and indefinite, Applicants have amended claim 60 to clarify that the target lipid is a phosphorylation product of a reaction between a phosphoinositide kinase and a substrate phosphoinositide lipid and respectfully argue that the amendments to claim 60 in combination with the amendments to claim 49 overcome the Examiner's rejection.

In view of the foregoing, Applicants respectfully request that the Examiner's rejection of claims 49-58 and 60-66 under 35 U.S.C. 112, second paragraph be withdrawn.

It is believed that an extension of 3 months is required. Therefore, a Petition for Extension of Time as required under 37 C.F.R. §1.17(a) is enclosed. Also, a Notice of Loss of Entitlement to Small Entity Status is enclosed.

A credit card payment form authorizing the charge of \$1020.00 for a 3-month extension of time is attached herewith. It is believed that no additional fee is currently due. In the event that an additional fee is deemed necessary or overpayment due in connection with this response, the undersigned authorizes the charge to be applied to Deposit Account No. 50-2679.

Respectfully Submitted,

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Date

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